

### **REMARKS**

Reconsideration of the subject application in view of the preceding amendments and the following remarks is respectfully requested.

Claim 1-6 are pending in this application. In this amendment, Claims 1 and 5 have been amended. No new matter has been added to the subject application by this amendment, nor have any new issues been raised.

Applicant reserves the right to pursue patent protection for claims of varying scope directed to any subject matter cancelled by this amendment, or other subject matter contained in the instant application, in any application filed hereafter which claims priority of the instant application.

### **Status of Application and Claims**

In the outstanding Office Action, the Examiner indicated that the terminal disclaimer filed on November 12, 2004 is not acceptable because the person who signed the terminal disclaimer is not recognized as an officer of the assignee, and he has not been established as being authorized to act on behalf of the assignee. Thus, Claims 1-6 were again rejected under the judicially created doctrine of obviousness-type double patenting.

Claim 1 also stands objected to because of informalities in the claim language. The Examiner asserts that "the first end bristle portions" should read "the first bristle end portions" in line 7 of Claim 1.

Claims 1-6 stand rejected under 35 U.S.C. §102(b) as being purportedly anticipated by U.S. Patent No. 4,873, 992 to Bayne (hereinafter referred to as "Bayne"). Claims 1-6 also stand rejected under 35 U.S.C. §102(e) as being purportedly anticipated by U.S. Patent No. 6,346,087 to Peltier (hereinafter referred to as "Peltier"). Claims 1-3, 5 and 6 also stand rejected under 35 U.S.C. §102(b) as being purportedly anticipated by U.S. Des. Patent No. 288,988 to Fomby (hereinafter referred to as "Fomby").

#### **Response by Applicant**

Applicant traverses the Examiner's rejections primarily because of the reasons set forth herein below. Applicant believes the claims as examined are directed to subject matter which is neither taught nor suggested by the cited references. By this amendment, Applicant has amended Claim 1 in an effort to advance prosecution and correct minor informalities, but not in acquiescence of any rejection thereto or because of any art cited in this or previous office actions. Applicant respectfully submits that the claims as now presented are also directed to subject matter which is neither taught nor suggested by the cited references. Furthermore, Applicant believes these claims are now in condition for allowance. For illustrative purposes, the rejections in the outstanding office action are discussed herein below as if these rejections were asserted against the claims as amended herein.

### **Claim 1 Objection**

Applicants have amended Claim 1 in a manner which is believed to also obviate the objection asserted by the Examiner in the outstanding Office Action. Thus, withdrawal of this rejection is respectfully requested.

### **Claim Rejections under 35 U.S.C. § 102**

#### **Rejection based on Bayne**

The 102 rejection of the instant application based on Bayne is hereby traversed.

Bayne discloses a device for simultaneously collecting cytology cell samples from the endocervix and exocervix. The Examiner points to the embodiment depicted in Fig. 3 of Bayne as anticipating the present invention as now claimed. Bayne discloses a brush 40 which includes an exocervical brush portion 42 and an endocervical brush portion 44. Exocervical brush portion 42 is provided with a "hollow shaft 46 which is sized and configured to telescope over the shaft of the endocervical bush portion 44" to "enable the shafts to rotate together when rotated by an attending physician." (Bayne; Col. 5, lins. 50-66) Brush portion 42 is provided with a disc 48 which in turn is provided with bristles 50. (Bayne; Col. 6, lines 5-9) Bayne describes bristles 50 as being long enough to enable the brushing surface to conform to the surface of the exocervix, even an irregularly shaped exocervix," among other things. (Bayne; Col. 6, lins. 10-13) It is described in Bayne that the attending physician inserts the brush into the vaginal cavity until the endocervical brush portion is located within the endocervical canal and the brushing surface of disc 48 is positioned against the patient's exocervix. The brush is then rotated one or two times to

scrape cell samples from the respective endocervix and exocervix. (Bayne; Col. 6, lins. 14-22)

In contrast to Bayne, Applicant now claims in amended independent Claim 1, "a device for obtaining a sample from a body cavity" which includes a "plurality of elongated flexible bristles of approximately uniform length," the bristles "defining opposing first and second bristle end portions," with the plurality of elongated flexible bristles being supported "in a direction substantially parallel to the longitudinal axis of the elongated portion to form a mop-like sample collecting member, wherein the mop-like sample collecting member is configured to obtain a sample through a mopping action," among other things.

As recited above, Bayne discloses that its brush has bristles which are used to "scrape" cell samples. The term "scrape" is used throughout Bayne, and Bayne uses no other term to describe how the cells are collected. Merriam-Webster Online ([www.m-w.com](http://www.m-w.com)) defines "scrape" as follows:

**1 a** : to remove from a surface by usually repeated strokes of an edged instrument

**b** : to make (a surface) smooth or clean with strokes of an edged instrument or an abrasive

**2 a** : to grate harshly over or against **b** : to damage or injure the surface of by contact with a rough surface **c** : to draw roughly or noisily over a surface

**3** : to collect by or as if by scraping

On Page 9 of the Action, the Examiner contends that it is inherent that sampling bristles would not be hardened to the extent that significant trauma is caused to the cervical

tissues. First, Applicant has not asserted that Bayne's bristles would be hardened to the extent that significant trauma would be caused to the cervical tissues. Rather, Applicant contends that Bayne use of the term "scrape" indicates that the bristles required for the sampling method Bayne indicated by using the term "scrape" is different from and does not anticipate Applicant's invention which as now claimed includes bristles capable of collecting samples through a "mopping action." In order to "scrape" samples from the cervical tissue, the bristles on Bayne's brush would have to be hardened, although this may not require bristles hard enough to cause significant trauma to the cervical tissue during sampling.

Also, the Examiner has provided no support for his contention that one skilled in the art would develop an alternate interpretation of Bayne's use of the term "scrape" to avoid using bristles that would cause significant trauma, and that interpretation would anticipate Applicant's invention as now claimed. Besides, the history of medical practice has included many procedures that caused trauma, and even present medical practice includes procedures that are often considered invasive and traumatic.

Furthermore, Bayne discloses a brush with bristles that "scrape" samples without any teaching or disclosure that one skilled in the art should select bristles less than a particular hardness to avoid causing trauma to the cervical tissue during use.

Applicant believes that one skilled in the art would interpret "scrape" as used by Bayne to mean a brush with bristles that are sufficiently hard enough to abrasively remove cellular samples from the cervix. Regardless of whether a brush according to Bayne incorporates bristles that abrasively removes cells in manner that causes significant trauma,

or little to no trauma, the meaning of the term "scrape" can not be stretched so far as to make Bayne anticipate a brush having bristles that form a "mop-like" sample collecting member capable of collecting cells through a "mopping action," among other things, as now claimed in independent Claims 1 and 5. The Examiner has provided no support for such an expansion of the definition of the term "scrape" as used in Bayne, to anticipate Applicant's invention as now claimed.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the... claim. Richardson v. Suzuki Motor Co., 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

In the present matter, every element of Applicant's claimed invention is not identically shown in the Bayne reference, either expressly or inherently. For example, the Bayne reference does not disclose a mop-like sample collecting member capable of collecting cells through a mopping action, among other things, as now claimed by Applicant in independent Claims 1 and 5. Thus, based on the standards set forth by 35 U.S.C. §102, the instant 102 rejection can not be sustained and therefore must be withdrawn.

Rejection based on Peltier

The 102 rejection of the instant application based on Peltier is hereby traversed.

Peltier discloses a flask for preparing a fixative-based cytological suspension which is provided with an opening which is intended for receiving a brush for cytological sampling. (Peltier; Col. 1, lins. 35-38) The brush is detachably fastened to a manipulation handle. (Peltier; Col. 1, lins. 61-63) After sampling, the brush is introduced into the flask through an open end that includes "abutment means for the brush," which means "enable the brush to be locked in the flask once the practitioner has introduced it into the flask and therefore to be detached from the handle by simply drawing on the latter." (Peltier; Col. 1, lin. 64 – Col. 2, lin. 4)

Paragraph 6 of the outstanding office action, reprinted below, includes the grounds for the 102 rejection of the present invention based on Peltier.

The brush 3 includes a plurality of elongated flexible bristles of approximately uniform length (at least those aligned with the elongated portion of the handle) connected to a handle including an elongated portion and a head portion to form a mop-like sample collecting member (see Fig. 1). The bristles extend from the head portion in a direction that is substantially parallel to the longitudinal axis of the handle. The head portion and the elongated portion are substantially cylindrical and the head portion is of a greater diameter than the elongated portions. The bristles have a modulus of elasticity that forms a soft surface having a substantially symmetrical shape.

Claim 1, as amended, is directed to a device for obtaining a sample from a body cavity that includes "a plurality of elongated flexible bristles of approximately uniform length defining opposing first and second bristle end portions" and "a handle having an elongated portion and a head portion configured to secure the first bristle end portions

therein and support the plurality of elongated flexible bristles in a direction substantially parallel to the longitudinal axis of the elongated portion to form a mop-like sample collecting member, wherein the mop-like sample collecting member is configured to obtain a sample through a mopping action."

In independent Claim 5, Applicant claims "a brush for self-sampling of cervical tissue" which includes "a plurality of bristles of approximately uniform length," wherein "each bristle of the plurality of bristles has a modulus of elasticity to form a mop-like sampling head having a soft surface area sufficient to acquire a sample of cervical tissue through a mopping action," among other things.

Claim 1 and Claim 5, as presented herein, recite elements which are fully supported by the instant application. Applicant points out that Peltier neither discloses each and every element claimed by Applicant in the amended claims, nor does Peltier show the identical invention now claimed by Applicant in as complete detail as is contained in the amended claims.

For example, in Claim 1 Applicant claims a device having a "plurality of elongated flexible bristles" that are supported to form a "mop-like sample collecting member." Peltier does not disclose whether the brush described in the patent and shown in the figure has bristles that are flexible or not, or whether its brush forms a mop-like sample collecting member capable of collecting samples through a mopping action, as now claimed by Applicant. Indeed, if Peltier discloses a brush at all, it appears to be simply for purposes of illustrating features associated with the flask, which is the focus of the patent.



Peltier does not even contain the word "bristles" or any other word meaning the same thing within the patent disclosure, let alone describe features that could provide any support for a 102 rejection of the claims as now presented. Based on Peltier's figure and disclosure, it could be argued that the brush in Peltier has bristles which are extremely stiff and could not possibly form a mop-like sampling member as claimed by Applicant. The bristles in the Peltier brush look stiff to Applicant. The point is, without a description of the bristles of the brush disclosed in Peltier, this 102 rejection of the amended claims is based on conjecture and unsupported. See W.L. Gore & Assoc., Inc. v. Garlock, Inc., 721 F.2d 1540 (anticipation can not be based on conjecture).

As noted above, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, supra. The identical invention must be shown in as complete detail as is contained in the... claim. Richardson v. Suzuki Motor Co., supra.

In the present matter, every element of Applicant's claimed invention is not identically shown in the Peltier reference, either expressly or inherently. For example, the Peltier reference does not disclose a mop-like sample collecting member capable of collecting cells through a mopping action, among other things, as now claimed by Applicant in independent Claims 1 and 5. Thus, based on the standards set forth by 35 U.S.C. §102, the instant 102 rejection can not be sustained and therefore must be withdrawn.

Rejection based on Fomby

The 102 rejection of the instant application based on Fomby is hereby traversed.

Fomby is a design patent that discloses an animal medicine applicator brush.

Paragraph 7 of the outstanding office action, reprinted below, includes the grounds for the 102 rejection of the present invention based on Fomby.

Fomby teaches a brush that is capable of obtaining a sample from a body cavity. The brush includes a plurality of elongated flexible bristles of approximately uniform length connected to a handle including an elongated portion and a head portion to form a mop-like sample collecting member. The bristles extend from the head portion in a direction that is substantially parallel to the longitudinal axis of the handle. The head portion and the elongated portion are substantially cylindrical. The bristles have a modulus of elasticity that forms a soft surface having a substantially symmetrical shape.

Claim 1, as amended, is directed to a device for obtaining a sample from a body cavity that includes "a plurality of elongated flexible bristles of approximately uniform length defining opposing first and second bristle end portions" and "a handle having an elongated portion and a head portion configured to secure the first bristle end portions therein and support the plurality of elongated flexible bristles in a direction substantially parallel to the longitudinal axis of the elongated portion to form a mop-like sample collecting member, wherein the mop-like sample collecting member is configured to obtain a sample through a mopping action."

In independent Claim 5, Applicant claims "a brush for self-sampling of cervical tissue" which includes "a plurality of bristles of approximately uniform length," wherein "each bristle of the plurality of bristles has a modulus of elasticity to form a mop-like

sampling head having a soft surface area sufficient to acquire a sample of cervical tissue through a mopping action," among other things.

Claim 1 and Claim 5, as presented herein, recite elements which are fully supported by the instant application. Applicant points out that Fomby neither discloses each and every element claimed by Applicant in the amended claims, nor does Fomby show the identical invention now claimed by Applicant in as complete detail as is contained in the amended claims.

For example, in Claim 1 Applicant claims a device having a "plurality of elongated flexible bristles" that are supported to form a "mop-like sample collecting member." Fomby does not disclose whether the brush described in the patent and shown in the figures has bristles that are flexible or not, or whether its brush forms a mop-like sample collecting member capable of collecting samples through a mopping action, as now claimed by Applicant.

Fomby discloses an animal medicine applicator brush, and that represents the entire extent of the written disclosure. It would seem that an animal medicine applicator brush, which presumably entails applying medicine to correct a malady on an the skin or coat of an animal, would be of different construction than a mop-like sample collecting member for collecting cervical samples. Applicant points out that the Examiner has not provided any further evidence that would suggest that the animal medicine applicator brush as disclosed by Fomby would actually be suitable for use as a mop-like cervical sample collecting member that collects cervical samples from the cervix through a mopping action. The Examiner has asserted that the animal medicine applicator brush of Fomby

anticipates a mop-like sampling member, as claimed by Applicant, but Fomby includes no disclosure that suggests such features and the Examiner has provided no evidence to support his assertion.

Clearly, the Examiner's assertion regarding the bristles is thus based on conjecture as to the features of the brush shown in the figures. As noted above, anticipation can not be based on conjecture. W.L. Gore & Assoc., Inc. v. Garlock, Inc., *infra*.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, *supra*. The identical invention must be shown in as complete detail as is contained in the... claim. Richardson v. Suzuki Motor Co., *supra*.

In the present matter, every element of Applicant's claimed invention is not identically shown in the Fomby reference, either expressly or inherently. For example, the Fomby reference does not disclose a mop-like sample collecting member capable of collecting cells through a mopping action, among other things, as now claimed by Applicant in independent Claims 1 and 5. Thus, based on the standards set forth by 35 U.S.C. §102, the instant 102 rejection can not be sustained and therefore must be withdrawn.

### **Conclusion**

Applicants believe that the amendment to the specification contained herein (namely the inclusion of a reference to related applications and their status), places the

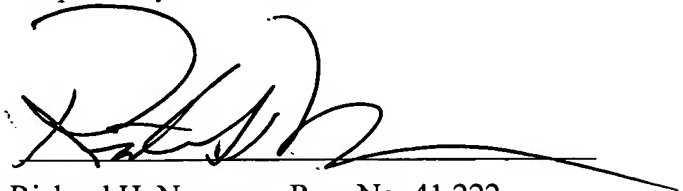
instant application in compliance with all conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §120.

Amended Claims 1 and 5 contain limitations which are not taught or suggested by Bayne, Peltier or Fomby. Thus, these claims are not anticipated by Bayne, Peltier or Fomby. Since amended independent Claim 1 and amended independent Claim 5 contain limitations which are neither taught nor suggested by Bayne, Peltier or Fomby, and the claims that depend from these claims, namely Claims 2-4 and 6, provide further limitations thereto, these claims are also not anticipated by Bayne, Peltier or Fomby.

A terminal disclaimer filed concurrently herewith which Applicant believes will be acceptable. Accordingly, it is respectfully submitted that as a result of this filing, all of the claims presently pending in this application are in condition for allowance, and such action is earnestly solicited.

If the Examiner believes that a personal or telephonic interview may facilitate resolution of any remaining matters, Applicant's representative may be contacted at the number indicated below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'R. Newman', with a long horizontal flourish extending to the right.

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